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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/346,069	07/01/1999	BRUCE A. KEYT	A-/62326-2/R	1979

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EXAMINER	
KAUFMAN, CLAIRE M	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/346,069	KEYT ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,18 and 34-59* is/are pending in the application.

4a) Of the above claim(s) *49-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,18 and 34-47* is/are rejected.

7)☒ Claim(s) *48* is/are objected to.

8)☒ Claim(s) *15,18 and 34-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 7/23/03 has been entered.

Newly submitted claims 49-59 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are direct to a method of modulating endothelial cell growth with the composition of claim 34. Even though this method is different from the method of claim 16 originally presented, the reasons for distinctness are the same as set forth in the original restriction (paper #9), which include different use for the composition, different classification and different search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 49-59 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicants argue that according to MPEP 809.03, example (D), the newly presented claims are linked and should not be restricted. The argument has been fully considered, but is not persuasive. While the process claims require the product, they are not so linked by a common technical feature such that the product could not be used in a materially different process. These inventions are properly restricted, but once the product is allowable and if the process claims contain all the limitations of the product claims by dependency or other means, the process claims will then be examined as explained immediately below.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Response to Arguments

The rejections of claims 19-33 are moot in view of the cancellation of the claims.

The rejection under 35 USC 112, first paragraph, for new matter is withdrawn in view of the amendment to the specification.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Inventorship

The previous request by Applicants for change of inventorship is withdrawn in view of the current request stating that due to the most recent amendment, no change is needed.

Double Patenting

Claim 18 remains and new claim 34 is rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 6,057,428 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent, for the reasons set forth in the previous Office action (paper #22, p. 4).

Claim 15 remains and new claims 35-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,057,428, for the reasons set forth in the previous Office action (paper #22, p. 4).

Note that neither the specification nor the prior art clearly distinguishes between a "purified" and an "isolated" polypeptide.

Applicant's intention to postpone addressing the rejection until subject matter is indicated as allowable and in the event that claims are amended remains acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Tischer et al. (US Patent 5,219,739, reference 11 cited by Applicants).

Tischer et al. teach both the human and bovine VEGF protein (Figures 7 and 6, respectively). Amino acids 63, 64, 67, 82, 84, 86, and 79, 83 of bovine VEGF differ from the native human VEGF of Figure 7. These residues fall within the range of residues at positions about 60-70 that make up the FLT-1 region and position about 78-95 that make up the KDR region. While Tischer et al. are silent as to differential binding affinities of the bovine compared to native human VEGF, one would reasonably expect, absence evidence to the contrary, that binding affinities would be different--even if only minutely different--because it is generally accepted by those of ordinary skill in the ligand/receptor art that species homologues of a ligand

which have different sequences will have different affinities for the same receptor.

As discussed in a previous Office action (paper #15, bottom of p. 6), the examiner maintains that "modification" does not require human intervention. The bovine VEGF is modified relative to the human VEGF as disclosed by Tischer. Therefore, the limitations of the claim is met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tischer et al. (US Patent 5,219,739).

Tischer et al. is relied upon for the teachings as applied to the claims above. Tischer et al. also teach conditioned medium containing secreted human VEGF protein (Examples 9 and 13), which constitutes a composition comprising a VEGF and a pharmaceutically acceptable carrier. The different binding properties of the forms of VEGF and their therapeutic advantages are also discussed (col. 2, lines 22-61). Tischer et al. do not teach such a composition comprising bovine VEGF.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce secreted bovine VEGF as taught by Tischer et al. for human VEGF in order to compare binding properties of the different VEGF proteins and evaluate their therapeutic potential as suggested by Tischer et al.

Note that adoption of wording used in amended claims 15 and 18 would obviate the above art rejections.

Conclusion

Claim 48 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571)272-0873. Dr. Kaufman can generally be reached Monday, Tuesday and Thursday from 8:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571)272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Claire M. Kaufman, Ph.D.
Patent Examiner, Art Unit 1646
April 29, 2004

LORRAINE SPECTOR
PRIMARY EXAMINER